

# **EXHIBIT 1**

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

**This document relates to:**

*The County of Summit, Ohio, et al., v.  
Purdue Pharma L.P., et al., Case No. 18-OP-  
45090 (N.D. Ohio)*

*The County of Cuyahoga v. Purdue Pharma  
L.P., et al., Case No. 17-OP-45004 (N.D.  
Ohio); and*

*City of Cleveland v. AmerisourceBergen  
Drug Corp., et al., Case No. 18-OP-45132  
(N.D. Ohio).*

**MDL No. 2804**

**Case No. 17-md-2804**

**Judge Dan Aaron Polster**

**VALLI BALDASSANO'S RESPONSES TO PLAINTIFFS' DEPOSITION BY WRITTEN  
QUESTIONS**

Pursuant to Special Master David R. Cohen's January 10, 2019 Order on Agenda Item 112, Valli Baldassano, by and through her undersigned counsel, hereby provides the following Responses to Plaintiffs' Deposition by Written Questions. Valli Baldassano's counsel provides the following Objections to Plaintiffs' Deposition by Written Questions.

**RESPONSES**

**Background**

1. State your full name, residence and occupation.

**Answer:** My maiden name is Valli Frances Baldassano and my current married name is Valli Frances Bellapigna. I live at [REDACTED]. I am an attorney.

2. State the dates, job titles and duties with regard to your employment with Cephalon.

**Answer:** My work at Cephalon began on October 27, 2007, when I became its Executive Vice President and Chief Compliance Officer. In this role, I reported directly to Cephalon's Chief Executive Officer and the Audit Committee of its Board of Directors. My duties included ensuring the effectiveness of Cephalon's Compliance program; ensuring that Cephalon's Compliance Program met or exceeded the requirements of all relevant requirements, guidance, and government regulator expectations; guiding and contributing to the continuous improvement of Cephalon's Compliance Program; negotiating a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services; overseeing Cephalon's Compliance department's involvement with the CIA once implemented; and providing routine reporting with regard to Cephalon's Compliance Program to, among others, the OIG, Cephalon's Board of Directors, Audit Committee, management, and employees on the Compliance Program generally and on specific compliance issues. Around 2009, my duties expanded to include overseeing Cephalon's Quality Assurance department. My employment ended on December 31, 2011.

Prior to Cephalon, and after graduating law school, I worked as an Assistant U.S. Attorney in the criminal division of the Eastern District of Pennsylvania, where I focused on healthcare fraud. In 1998, I was the Senior Counsel for Compliance and Fraud at Independence Blue Cross. Between 1998 and 2003, I was the Senior Director for Global Compliance at Pharmacia & Upjohn (which became Pharmacia Corp, which was acquired by Pfizer). After that, the new management of Tyco International hired me as Chief Compliance Counsel to create the company's compliance program. In January 2004, I was recruited by Schering-Plough to negotiate and implement two Corporate Integrity Agreements and an FCPA (Foreign Corrupt Practices Act) consent decree with the Securities and Exchange Commission; I served as their

VP of Global Compliance for Global Prescription Business and Global Specialty Operations until March 2007. I then joined Fox Rothschild in their Criminal Defense department, where I worked immediately before joining Cephalon.

3. Do you agree that as Cephalon's Chief Compliance Officer you reported directly to the Chairman and CEO of Cephalon during your employment with Cephalon? If not, who did you directly report to?

**Answer:** Yes, as Cephalon's Chief Compliance Officer, I reported directly to the Chairman and CEO. However, to ensure my independence, I also had direct reporting responsibility, and unrestricted access, to the Audit Committee of Cephalon's Board of Directors.

4. At the time, the Chairman and CEO of Cephalon was Frank Baldino?

**Answer:** When I began at Cephalon, Frank Baldino was the Chairman and CEO. In 2010, Mr. Baldino died and Kevin Buchi replaced him as Cephalon's CEO. Cephalon merged with Teva in October 2011, and Shlomo Yanai was the President and CEO of Teva. Mr. Yanai was still the President and CEO of Teva when I left in December 2011.

5. Have you ever been deposed before?

**Answer:** Yes.

6. If so, what is the case name of your prior deposition(s)?

**Answer:** When I was a prosecutor in the U.S. Attorney's Office in the Eastern District of Pennsylvania, a defense attorney was sued by his client for malpractice. I was deposed as a fact witness in that case. I do not recall the name of the case.

7. Did you read or listen to any witness statement or deposition prior to this deposition by written questions? If so, please list the names of the witness statements and/or depositions you read or to which you listened.

33. According to the CIA, TEVA\_MDL\_A\_07201724, Cephalon was to notify health care providers or entities that Cephalon currently detailed within “the terms of the global settlement with the United States, including an explanation of the conduct to which Cephalon pled guilty and the conduct resolved by the civil settlement”, correct?

**Answer:** Yes, this was the Dear Doctor letter referenced in response to question 17. We also created a phone line for healthcare professionals to call in response to receiving the Dear Doctor letter. Any responses to our Dear Doctor letter were reported to the OIG.

34. Do you agree that Attachment A to the CIA, TEVA\_MDL\_A\_07201746, is a true and accurate copy of the letter sent to health care providers?

**Answer:** Yes. This was negotiated with and approved by the OIG.

35. The United States Government alleged that Cephalon unlawfully promoted three drugs, correct?

**Answer:** The conduct alleged by the U.S. Government is set forth in the settlement documents. It related to three drugs. While the government alleged off-label promotion of those drugs, it did not allege that Cephalon made any untruthful or misleading statements in promoting those drugs.

36. The United States Government alleged that Cephalon unlawfully promoted Actiq, correct?

**Answer:** The conduct alleged by the U.S. Government is set forth in the settlement documents. It related to three drugs. While the government alleged off-label promotion of Actiq, it did not allege that Cephalon made any untruthful or misleading statements in promoting Actiq.

37. Cephalon pled guilty to a misdemeanor criminal violation, correct?

**Answer:** Yes, Cephalon pled guilty to a single misdemeanor of off-label promotion during a nine-month period in 2001.

46. Please review TEVA \_MDL\_A\_07201767. You agree that the United States Attorney alleged that “[u]sing the mantra ‘pain is pain,’ Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote this drug for many uses other than breakthrough cancer pain”, correct?

**Answer:** The document speaks for itself. However, I do not recall ever hearing “pain is pain” as a mantra at Cephalon.

47. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree Cephalon used the mantra ‘pain is pain’?

**Objection:** Vague; calls for speculation.

**Answer:** When I joined Cephalon, I had no information that Cephalon was using the phrase “pain is pain” as a mantra or in any way to encourage off-label promotion. I never heard that phrase used. In fact, I can only recall ever reading about that phrase being used once, by Frank Baldino when he was speaking to investors. This was not in the context of sales, promotion, marketing, or training.

48. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners?

**Objection:** Vague; calls for speculation.

**Answer:** No. Cephalon stopped promoting Actiq before I joined the company. Based on the extensive knowledge of Cephalon’s promotional practices that I gained through my role as Chief Compliance Officer, Cephalon instructed its sales representatives to only call on healthcare providers when it was reasonable to believe that their practice included patients that could be treated with a Cephalon product for an on-label indication, and that it was likely that they would

treat the on-label condition based on the nature of their practice. Sales representatives were not allowed to call on healthcare providers who informed the representative that they would not treat patients on-label, who belonged to certain specialties, or who were identified on the company's lists maintained to track specific physicians that the company determined were debarred or were otherwise inappropriate to be called upon.

49. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon instructed the Actiq sales representatives to promote this drug for many uses other than breakthrough cancer pain?

**Objection:** Vague; calls for speculation.

**Answer:** No. Cephalon stopped promoting Actiq before I joined the company. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, Cephalon instructed sales representatives to promote its products (including Fentora) only for on-label uses.

50. Please review TEVA \_MDL\_A\_07201767. You agree that the United States Attorney alleged that "Cephalon trained its sales representatives on particular questioning techniques to use with their customer physicians to prompt off-label conversations about the company's drugs," correct?

**Answer:** Yes, that is what was alleged.

51. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon trained its sales representatives on particular questioning techniques to use with their customer physicians to prompt off-label conversations about the company's drugs?

**Objection:** Vague; calls for speculation.

**Answer:** No. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, Cephalon did not train its sales representatives to use that technique.

52. Please review TEVA \_MDL\_A\_07201767. You agree that the United States Attorney alleged that "Cephalon compensated its sales representatives through sales quotas and a bonus structure designed to encourage off-label promotion of its drugs", correct?

**Answer:** Yes, that is what was alleged.

53. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon compensated its sales representatives through sales quotas and a bonus structure designed to encourage off-label promotion of its drugs?

**Objection:** Vague; calls for speculation.

**Answer:** No. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, the sales quotas and bonuses were not designed to do that. They encouraged promotion and sales but not off-label promotion. During my time at Cephalon, the Compliance department had to sign off on any sales representative's bonus to make sure that those receiving bonuses were in compliance with the law and with Company policies, and did not encourage off-label promotion.

54. Please review TEVA \_MDL\_A\_07201767. You agree that the United States Attorney alleged that "sales representatives generally could only reach their sales goals by promoting and selling off-label", correct?

**Answer:** Yes, that is what was alleged.



**Answer:** No. Based on the extensive knowledge of Cephalon's policies and procedures that I gained through my role as Chief Compliance Officer, physicians were selected to be consultants based upon clinical or other relevant experience or background, and not based on their volume of business or of on- or off-label scripts.

65. Please review TEVA \_MDL\_A\_07201768. You agree that the United States Attorney alleged that "Cephalon undertook these promotions for its own gain, despite the risk to patients' health and lives", correct?

**Answer:** Yes, that is what was alleged.

66. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon undertook these promotions for its own gain?

**Objection:** Vague; calls for speculation.

**Answer:** No. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, Cephalon did not undertake these promotions for the reasons alleged. On the contrary, Cephalon had an industry-leading compliance program and continued to enhance and refine its compliance policies, develop additional policies, conduct inquiries into any allegations that an employee or speaker had violated company policy or engaged in off-label promotion, and took appropriate disciplinary action when warranted.

67. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon undertook these promotions and thereby increased the risk to patients' health and lives?

**Objection:** Vague; calls for speculation.

**Answer:** No.

68. Please review TEVA\_MDL\_A\_07201774-07201788. You agree that Cephalon signed a guilty plea agreement under Fed.R.Crim.P. 11(C)(1)(C), pleading guilty to a one-count misdemeanor information charging it with misbranding under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, correct?

**Answer:** Yes, Cephalon signed a guilty plea agreement, pleading guilty to a one-count misdemeanor information charging it with misbranding under the Food, Drug and Cosmetic Act, for promoting three drugs for uses not approved by the FDA for a nine-month period between January 2001 and October 1, 2001. Cephalon was not alleged to have made and was not charged with making any untruthful or misleading statements in promoting these three products.

69. Please review TEVA\_MDL\_A\_07201774-07201788. You agree that you reviewed and kept this document in the course of regularly conducted business and as a part of your role at Cephalon, correct?

**Answer:** I agree that I reviewed this document during my employment at Cephalon but do not know if I kept it.

70. Please review TEVA\_MDL\_A\_07201774-07201788. You agree that you reviewed and relied upon the information in this document as a part of your role at Cephalon, correct?

**Answer:** Yes.

71. Please review TEVA\_MDL\_A\_07201774-07201788. You agree that Cephalon signed a guilty plea agreement under Fed.R.Crim.P. 11(C)(1)(C), pleading guilty to a one-count misdemeanor information charging it with misbranding of the drug Actiq, among others, under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, correct?

**Answer:** Yes, Cephalon signed a guilty plea agreement, pleading guilty to a one-count misdemeanor information charging it with misbranding under the Food, Drug and Cosmetic Act, for promoting three products for uses not approved by the FDA for a nine-month period between January 2001 and October 1, 2001. Cephalon was not alleged to have made and was not charged with making any untruthful or misleading statements in promoting these three products.

72. Please review TEVA\_MDL\_A\_07201774-07201788. You agree that Cephalon signed a guilty plea agreement under Fed.R.Crim.P. 11(C)(1)(C), admitting that Cephalon “promoted Actiq for uses not approved by the FDA, including for non-cancer pain uses, such as injuries and migraines”, correct?

**Answer:** Yes. That is what the guilty plea says. To be clear, while Cephalon admitted to off-label marketing for a nine-month period of time, between January 2001 and October 1, 2001, the government did not allege that Cephalon made any untruthful or misleading statements in its promotion of Actiq.

73. Please review TEVA\_MDL\_A\_07201774-07201778-07201779. You agree that Cephalon stipulated that “[b]etween January 2001 and October 1, 2001, Cephalon promoted Actiq for uses not approved by the FDA, including for non-cancer pain uses, such as injuries and migraines. Cephalon’s promotion of Actiq for these additional intended uses violated 21 U.S.C. § 352(f)(1), because Actiq’s labeling did not bear adequate directions for each of the drug’s intended uses”, correct?

**Answer:** Yes. That is what the stipulation says. To be clear, while Cephalon stipulated that it promoted Actiq for uses not approved by the FDA for a nine-month period of time between January 2001 and October 1, 2001, the Government did not allege that Cephalon made any untruthful or misleading statements in its promotion of Actiq.

90. Please review TEVA\_MDL\_A\_07201619-07201620. You agree that the U.S. Department of Justice's Press Release states, "Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results", correct?

**Answer:** Yes, that is what it states.

91. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon promoted Actiq for use in patients who were not yet opioid-tolerant?

**Objection:** Vague; calls for speculation.

**Answer:** No. Cephalon stopped promoting Actiq before I joined the company. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, Cephalon did not promote Actiq or Fentora for use in patients who were not yet opioid-tolerant. Furthermore, Cephalon submitted all product marketing and promotional pieces for Actiq and Fentora to the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) for their review as required by law. Thus, the FDA had the opportunity to review, evaluate, and identify anything it deemed inappropriate in the promotional materials used for Actiq and Fentora. This process, along with the extensive internal processes Cephalon had in place (which required multi-disciplinary review of all materials before they were ever used), ensured that Cephalon's promotional materials were not false or misleading.

92. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon promoted Actiq for use in patients for whom it could have life-threatening results?

**Objection:** Vague; calls for speculation.

**Answer:** Cephalon stopped promoting Actiq before I joined. I agree that the product could hurt a patient, even when used on-label. The specific risks associated with Actiq are described in detail in the FDA-approved product label.

93. Please review TEVA\_MDL\_A\_07201620. You agree that the U.S. Department of Justice's Press Release states, "Defendant Cephalon undertook its off-label promotional practices using a variety of techniques. It trained its sales force to disregard the restrictions of the FDA-approved label, and to promote the drugs for off-label uses. For example, the Actiq label stated that the drug was for 'opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids.' Using the mantra 'pain is pain,' Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many uses other than breakthrough cancer pain", correct?

**Answer:** Yes, it states that.

94. During your investigation as Chief Compliance Officer at Cephalon, did you find evidence that Cephalon trained its sales force to disregard the restrictions of the FDA-approved label, and to promote the drugs for off-label uses?

**Objection:** Vague.

**Answer:** No. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, Cephalon did not train its sales force to disregard the restrictions of the FDA-approved label and to promote drugs for off-label uses. To the contrary, Cephalon sales and marketing personnel were trained to promote Cephalon's products only on-label, and were required to report any suspected violations of this policy.

were required to sign a contract providing (among other things) that “Speaker must never use their own slides or other presentation materials for any purpose during the course of a [Cephalon Speaker Program],” and that “For product specific clinical presentations . . . In response to an ‘on-label’ question in the Q&A session, Speaker may answer the question verbally and/or use the Cephalon-approved promotional slides. In response to an ‘off-label’ question in the Q&A session, Speaker must not display or distribute any slides or other materials, but rather, if Speaker chooses, may provide a verbal answer to the question. Speaker’s answers to questions must present the information in an accurate, fair and balanced, and objective manner, and must disclose the basis for answering the question. . . . If the answer to an unsolicited question includes any ‘off-label’ information, then Speaker must state that such information relates to an ‘off-label’ use, indication, dose, etc.

101. During your investigation as Chief Compliance Officer at Cephalon, did you find evidence that Cephalon funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs?

**Objection:** Vague.

**Answer:** No. Based on the extensive knowledge of Cephalon’s policies and procedures that I gained through my role as Chief Compliance Officer, Cephalon did not fund continuing medical education programs to promote off-label uses of its drugs, including Actiq and Fentora. A division of Cephalon’s Medical Affairs department called Medical Education was in charge of receiving, reviewing, and approving grant requests for continuing medical education from third parties. Funds were distributed by Medical Affairs, and Sales and Marketing did not have a role in the process. In addition, all funding was subject to the terms of a contract which provided (among other things) that “The Program is for scientific and educational purposes only . . . and is

not intended to promote a Cephalon product, directly or indirectly. . . . Provider shall retain full responsibility for control of the content of the Program and shall ensure that . . . The Program material/content will be objective, balanced and free from commercial bias. . . . Provider agrees that Cephalon shall not influence the content of the Program. Cephalon personnel will not attend content development meetings. . . . Provider will ensure meaningful disclosure to the audience of support from Cephalon and all other supporters if applicable and any significant relationship between individual Faculty and Cephalon.” I am unaware of any funding from Cephalon for continuing medical education that violated FDA requirements.

102. During your investigation as Chief Compliance Officer at Cephalon, did you find evidence that Cephalon funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of Actiq?

**Objection:** Vague.

**Answer:** No. See my response to question 101.

103. During your investigation as Chief Compliance Officer at Cephalon, did you find evidence that Cephalon funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of Actiq, in violation of the FDA’s requirements?

**Objection:** Vague.

**Answer:** No. See my response to question 101. Further, based on the extensive knowledge of Cephalon’s policies and procedures that I gained through my role as Chief Compliance Officer, Cephalon’s policies and procedures concerning medical information education programs complied with the FDA’s requirements.

104. Please review TEVA\_MDL\_A\_07201621. You agree that the U.S. Department of Justice’s Press Release states, “Today’s settlement demonstrates the government’s continued

scrutiny of sales and marketing practices by pharmaceutical companies that put profits ahead of the public health”, correct?

**Answer:** Yes, it states that.

105. Based upon your investigation as Chief Compliance Officer at Cephalon, did you find evidence that Cephalon engaged in off-label marketing of Actiq?

**Objection:** Vague.

**Answer:** Cephalon stopped promoting Actiq before I joined the company. I am aware that Cephalon stipulated that, between January 2001 and October 1, 2001, it promoted Actiq for uses not approved by the FDA. Based on the extensive knowledge of Cephalon’s promotional practices that I gained through my role as Chief Compliance Officer, I am not aware of Cephalon engaging in off-label marketing of Actiq or Fentora, outside of that.

106. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon engaged in off-label marketing of Actiq?

**Objection:** Vague; calls for speculation.

**Answer:** Cephalon stopped promoting Actiq before I joined the company. I am aware that Cephalon stipulated that, between January 2001 and October 1, 2001, it promoted Actiq for uses not approved by the FDA. Based on the extensive knowledge of Cephalon’s promotional practices that I gained through my role as Chief Compliance Officer, I am not aware of Cephalon engaging in off-label marketing of Actiq or Fentora, outside of that.

107. Based upon your investigation as Chief Compliance Officer at Cephalon, did you find evidence that Cephalon engaged in misbranding of Actiq?

**Objection:** Vague.



**Answer:** Cephalon stopped promoting Actiq before I joined the company. I am aware that Cephalon stipulated that, between January 2001 and October 1, 2001, it promoted Actiq for uses not approved by the FDA, and that the labeling did not bear adequate directions for each of the drug's intended uses. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, I am not aware of Cephalon engaging in misbranding of Actiq or Fentora, outside of that.

108. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon misbranded Actiq?

**Objection:** Vague; calls for speculation.

**Answer:** Cephalon stopped promoting Actiq before I joined the company. I am aware that Cephalon stipulated that, between January 2001 and October 1, 2001, it promoted Actiq for uses not approved by the FDA, and that the labeling did not bear adequate directions for each of the drug's intended uses. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, I am not aware of Cephalon misbranding Actiq or Fentora outside of that.

109. Based upon your investigation as Chief Compliance Officer at Cephalon, do you agree that Cephalon put profits ahead of the public health when it engaged in off-label marketing of Actiq?

**Objection:** Vague; calls for speculation.

**Answer:** No. Cephalon stopped promoting Actiq before I joined the company. Based on the extensive knowledge of Cephalon's promotional practices that I gained through my role as Chief Compliance Officer, I do not agree with that statement.

188. Please review TEVA\_MDL\_A\_03545893-03545894. You agree that you reviewed and kept this document in the course of regularly conducted business and as a part of your role at Cephalon, correct?

**Answer:** I agree that I reviewed this document during my employment at Cephalon but do not know if I kept it.

189. Please review TEVA\_MDL\_A\_03545893-03545894. You agree that you received this email in the regular course of your employment, correct?

**Answer:** Yes.

190. Please review TEVA\_MDL\_A\_03545893-03545894. You agree that you reviewed and kept this document in the course of regularly conducted business and as a part of your role at Cephalon, correct?

**Answer:** I agree that I reviewed this document during my employment at Cephalon but do not know if I kept it.

Dated: July 29, 2019

Respectfully submitted,

/s/ Steven A. Reed

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and Valli Baldassano*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on July 29, 2019, the foregoing has been served via email only to the following liaison counsel:

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*/s/ Rebecca J. Hillyer*

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Rebecca J. Hillyer

**VERIFICATION**

I, Valli Baldassano, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Ottsville, PA

Dated: July 29, 2019

/s/ Valli Baldassano

Valli Baldassano